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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/350,474 | 07/09/1999 | WILLIS L. WINSTROM | POC-99-1-1 | 8187 |

23531 7590 05/13/2002
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EXAMINER

LEVY, NEIL S

ART UNIT PAPER NUMBER

1616

DATE MAILED: 05/13/2002

20

Please find below and/or attached an Office communication concerning this application or proceeding.

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This is a communication from the examiner in charge of your application.
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OFFICE ACTION SUMMARY

- ☒ Responsive to communication(s) filed on 3/27/02
- ☐ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

- ☒ Claim(s) 1-10, 57-75, 77-85, 87, 99-103 is/are pending in the application.
- Of the above, claim(s) _____ is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 1-10, 57-75, 77-85, 87, 99-103 is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☐ Claims _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
- ☐ received.
- ☐ received in Application No. (Series Code/Serial Number) _____
- ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

- ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- ☐ Notice of Reference Cited, PTO-892
- ☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 18
- ☐ Interview Summary, PTO-413
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Notice of Informal Patent Application, PTO-152

- SEE OFFICE ACTION ON THE FOLLOWING PAGES -

RESPONSE
Due: 8/13/02
1st: 9/13/02
2nd: 10/13/02
3rd: 11/13/02
4th:

Receipt is acknowledged of RCE, IDS and amendment, each of 3/28/02.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-4, 8-10, 57, 60, 64, 67, 70, 75 and 101 are rejected under 35 U.S.C. 102(b) as being anticipated by King--52663477.

King uses fermentation broths (col. 2, line 1-31) as feed supplement, derived from antibiotic organism culture (col. 1, lines 7-14) of the instant invention (amphotericin). The dried mass (col. 2, line 57-61) is mixed with mineral (col. 3, lines 12-22) or edible feed soybean --(col. 4, lines 5-13). The antibiotic may have beneficial effect on animal. (col. 4, lines 19-21); the biomass is 5-35% active (col. 3, lines 29-33). The biomass is divided (col. 3, last paragraph) into particles, dried, thus being granules of a substantially uniform particle size and then blended with feed ingredients (col. 5, lines 15-35). The product is stable, thus, resistant to powdering (col. 2, line 55-58), of sufficient antibiotic activity (col. 4, lines 19-21); col. 5, lines 32-35) to treat an animal. Mineral and feed materials are used in admixture (col. 6, 2nd paragraph). The formulations are not compressed, since nowhere is compression disclosed. The composition can include soybean meal or flour, or fish meal (col. 4, lines 5-8, col. 5, lines 22-31; col. 6, line 5) thus, would include the instant claim amount of oil. Rice hulls (lines 5, col. 4) or limestone may be used.

Claims 57, 60-66, 70-73, 75, 87, 101-103 are rejected under 35 U.S.C. 102(b) as being anticipated by Klothern-4447421.

The rejection of record is maintained.

Applicant's arguments filed 3/28/02 have been fully considered but they are not persuasive. We agree Klothier compacts; however, this is not precluded from applicant's claims, and the Klothier composition is stated by applicant to have the instant granular, dust free form. Columns 3 and 4, and example 2 describe the preparations of chlortetracycline medicated feed, with added antibiotic (sulfa, penicillin). The medicated products are effective as medicinally thus, sufficient to treat the animal. As purported Klothier. The fermentation products are prepared as crude mixes, thus inclusive of the ferment solids and organism remnants.

Claims 1-10, 57-75, 77-85, 87, 99-103 are rejected under 35 U.S.C. 103(a) as being unpatentable over King 5266347 in view of Chapman 4211781 and Kemp et al 5908634 and Sobin et al 516080.

King (above) provides the instant composition, but fails to state that the composition is dustless, or uses oil per se in the preparation. Chapman (col. 2, line 67- col. 2, line 2) shows dusty is bad, and blending with a non-toxic oil (col. 3, lines 20-45) at 2-8% of a premix is good. The premix includes edibles—wheat middling and limestone. It is obvious that increasing oil in any feed supplement will reduce dust (line 68, col. 3-line 3, col. 4), Chapman fails to use a ferment. Kemp, does but of molasses, with added oxytetracycline or other antibiotics (col. 3, line 28-line 63, col. 4).

Sobin further shows the tetracycline fermentation process—filtered ferment is at col. 7, lines 20-26, acidified. Calcium complex is indicated at Example 1; salt formation obvious at col. 8, lines 70-line 1, col. 9. crystalline form is shown at col. 7, lines 52-61. this reference shows how the tetracyclines are prepared, thus, the use of these forms is

obvious as an added amount of antibiotic to achieve the required potency. Applicant has shown no criticality that the form of the added antibiotic is of any consequence. While Sobin shown potency determination, thus the use of any of these products.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made desiring to utilize an effective, stable, medicated feed, to use one of King, modified by Chapman, also teaching medicated feed, to reduce dust by using oil, and by Kemp, showing similar granular feed premixes, with addition of antibiotic of choice, and preparation thereof shown by Sobin in the case of tetracycline. King's use of antibiotic pre-mix as a ferment provides added benefits; but as it is well known in the veterinary arts and feed supplement compounding arts to provide the amount and concentration of an antibiotic to permit the desired antibiotic effect, if the amount is insufficient from a desired antibiotic source, added pure compound is used to bring potency to the desired level. Thus, the added incorporation of a desired antibiotic of the Kemp composition would be an obvious modification of Kin. In particular, potency would be desired to minimize the potential of low level antibiotic generating a resistant microbial strain unable to then be treated with that antibiotic.

All the critical elements of the instant are disclosed. The amounts of each ingredient are result effective parameters chosen to obtain the desired effects. It would be obvious to vary the form of each ingredient to optimize the effect desired, depending upon the particular pest microbe of interest, reduction of toxicity, cost minimization, palatability, stability animal species to be fed.

Applicant has not provided any objective evidence of criticality, nonobvious or unexpected results that the administration of the particular ingredients' or preparation provides any greater or different level of prior art expectation as claimed, and the use of ingredient for the functionality for which they are known to be used is not a basis for patentability.

The instant invention provides well known old art recognized compounds, with well known art recognized effects, applied by well known art recognized methods to achieve medicated feed as is well known in the art.

Claims 82-85 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The additional antibiotics is the "said" antibiotic of claim 77—implied is a form of the additional which is in fact, not the antibiotic of claim 77—i.e., are both forms a calcium complex of (claim 82) chlortet, (claim 84-oxytet.).

Applicant's arguments filed 3/28/02 have been fully considered but they are not persuasive. Applicant's arguments have been considered and reflections above have taken them into account. To the extent rejections have not been maintained, amendments and arguments were persuasive. However, it is not evident to examiner, where, if at all, explanation of the intended quantification of the objected to terminology is support in the specification. Substantially no support is evident for the term substantially—we could interpret the term to mean less dust than would cause respiratory disease as being substantially dustless, and yet have so much dust as to

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cause coughing. Or, it could mean no dust except a trace amount, as achieved by compacting, or it could mean that reduced by oil coating—which examiner finds as the one of the critical, but unclaimed generic aspects of the invention and known in the art.

Because applicant amended in accord with suggested terminology, although 112 rejection is no longer applicable, does not mean the claims are no longer anticipated or non obvious. An antibiotic level sufficient to treat an animal is, contrary to applicants arguments, in sufficient to overcome the prior art. The rejections explain why—but, more: treat does not require more than an administration. The instant claims would require a dosage amount, sufficient to ameliorate an antibacterial infection; in other words, at a higher level than a growth promoting effect, in order to overcome King. It is not clear if the dosages (p. 7) would overcome King; applicant discloses/Og/# to 3008/#.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Neil Levy whose telephone number is 308-2412. The examiner can normally be reached on Tuesday- Friday 7:00 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jose Dees can be reached on 308-4628. The fax phone numbers for the organization where this application or proceeding is assigned are 305-4556 for regular communications and 305-3592 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 308-1235.

Levy:mv
April 30, 2002

A handwritten signature in cursive script, appearing to read "Neil S. Levy".

NEIL S. LEVY
PRIMARY EXAMINER